

REMARKS

The present Amendment is responsive to the Official Action mailed February 26, 2009, and is timely filed within the shortened statutory period for filing a response. In the Official Action, the Examiner has maintained his rejection of the pending claims, claims 1-31 and 39-47, principally over the *Studer* (US 6,146,383) and *Young* (US 6,626,906) references. In addition, the Examiner has set forth several objections and non-prior art based rejections.

Addressing the objections first, the Examiner objected to the preamble of claims 2-18, 23-24, 27-28, and 30 as not including what the Examiner considers to be necessary language. Applicant has amended the preambles to include the language suggested by the Examiner, namely "bone fixation assembly" in lieu of simply "assembly," and believes that the objection is therefore met. The Examiner also objected to claim 19 and suggested amending "coupling member" found in lines 6 and 10 to "coupling element." Applicant has made the requested amendments, and likewise believes that the objection has been met.

For his non-prior art based rejections, the Examiner first rejected claims 1-23, 29-31, 39-40, 43, and 46-47 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner claims that the term "compressive ball ring" is not supported in the specification. The Examiner may recall that on October 15, 2008, the undersigned and the Examiner conducted an interview. During that interview, the Examiner suggested use of the term "compressive" in association with ball ring.¹ To be sure, the term compressive ball ring was intended to cover at least a ball ring that, as the Examiner states, acts such that "when a

¹ Refer to the Amendment filed November 11, 2008, pages 9-10. See also, for example, the amendment to claim 9 on even date.

locking nut exerts a radial force on the ball ring, the ball ring, in turn, exerts a compressive force onto a fixation element." To further clarify the rejected claims, Applicant has replaced the term "compressive" with the term "compressible." It is believed that this change reflects the understanding of the Examiner and is supported by the specification. Reconsideration is therefore respectfully requested.

The Examiner next rejected claims 1-23, 25-30, and 39-46 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claiming the subject matter which Applicant regards as the invention. In this regard, the Examiner points to claims 1, 19, 25-26, and 29 which cite "the head portion" following recitation of "a head portion of a fixation element." Even though these are claimed functionally, as the Examiner notes, it is submitted that the claiming method is proper. Elements may be referred to functionally to define a capability or purpose served by recited elements. *Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004). Nevertheless, Applicant has amended the claims to provide that the later referenced clause, "the head portion" specifically relate back to "the head portion of the fixation element," which is functionally claimed. It is believed that this amendment should clarify the claim by making certain that it is the head portion of the fixation element that is being referenced, and not some other undefined head portion. Reconsideration of the rejection is requested.

Claims 8-9 were rejected for referencing "the locking nut" without antecedent basis. Claim 8 has been amended to depend from claim 2, which includes the locking nut. Claim 9 depends from claim 8. Accordingly, the Examiner's rejection has been fully met.

Lastly, the Examiner reject claims 16-17 for claiming "the bore," without specifically referring to the first or second bore previously identified. Applicant has amended the claims to specifically relate back to the first bore, and it is therefore believed that the Examiner's rejection has been met.

In addition to the amendments addressed above, Applicant has reviewed the claims and has made further clarifying amendments. For example, the term "screw" referenced in claim 25 has been amended to "fixation element."

In the art-based rejections, the Examiner principally rejected the claims over *Studer* and *Young*, using 35 U.S.C. §103(a) as a basis, as mentioned above. For claims 1-5, 7-18, 25-31, 39, 41-42, and 44-47, the Examiner contends that *Studer* teaches each of the features with the exception of "a coupling element and compression element that allow a fixation element to perform not only axial movement but also linear movement." The Examiner finds such a teaching in *Young*, which discloses such linear movement.

As stated in response to earlier Actions, the proposed combination of *Studer* and *Young* is believed to be inappropriate, and the previous comments in this regard are incorporated herein by reference as if fully set out.

Of the rejected claims, claims 1, 25-26, 29, and 31 are independent. Claim 1 is exemplary. As amended, claim 1 recites (with emphasis added):

1. (currently amended) A bone fixation assembly comprising:

a unitary coupling element having a first bore having an axis, the first bore adapted to receive a head portion of a fixation element and to permit axial, sliding movement of the coupling element relative to the fixation element, the coupling element having a second bore adapted to receive a spinal rod;

a first locking element adapted to secure the head portion of the fixation element in the first bore at any point along the length of the head portion of the fixation element, wherein the first locking element comprises a ~~compressive~~ compressible ball ring; and

a second locking element adapted to secure the spinal rod in the second bore.

The Examiner contends that *Young* provides a "compressive member" 17 that enables compression. However, claim 1 does not simply recite a "compressive member", but rather a specific type of compressive member, namely a ball ring. Nowhere in *Young* is there shown a ball ring associated with the fixation element. The Examiner does contend that element 9 of *Studer* is a ball ring, but Applicant traverses this assertion. Element 9 of *Studer* is at best a ball, not a ball ring. Nor is it a compressible ball ring.

The term ring is defined as the area between two concentric circles. There are no concentric circles associated with *Studer's* ball.

Moreover, *Young's* ball ring is associated with the bore that supports the rod, not the bore that supports the fixation element. This is an important distinction as *Young* actually teaches away from use of a ball ring specifically with the fixation element.

For the foregoing reasons it is believed that the rejection cannot stand, and reconsideration is earnestly solicited.

In rejecting claims 19-24, 40, and 43, the Examiner states that *Studer* and *Young* teach the invention except where the invention is in preassembled form. First, based on the foregoing, it is not believed that the references teach the invention of claims 19-24, 40, and 43, and the rejection is

traversed on that point alone. Further, this rejection brings to light an important distinction between the present invention as claimed and the two references cited by the Examiner. In the present invention as claimed, the coupling can be fully assembled while permitting movement of the coupling with reference to the rod and the fixation element in a multitude of directions. Neither *Studer* nor *Young* support such a teaching. For example, in the *Studer* disclosure the coupling may not move linearly along the axis of the fixation element when assembled. This limits the surgeon's ability to fine tune the connections and align the components properly. The present invention as claimed overcomes this shortcoming and is therefore patentable over the *Studer* and *Young* references collectively for this additional reason. (See paragraph [0033], generally.)

Lastly, Applicant notes the Examiner's rejection of claim 6 over *Studer* and *Young* and in further view of *Errico* (US 5,776,135). It is not believed that additional comments are necessary with respect to the additional reference as such reference fails to teach the shortcomings noted above.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.


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Docket No.: SPINE 3.0-414

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By 
Scott E. Charney
Registration No.: 51,548
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant

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